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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/684,628	MCBRIDE ET AL.
Examiner	Art Unit	
Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 07 July 2003 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-107 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,4,5,15,16,20-44,46,48,60,61,64-67,70,77,88-96 and 102-107 is/are rejected.

7) Claim(s) 3,6-14,17-19,45,47,49-59,62,63,68,69,71-76,78-87 and 97-101 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6 6) Other: _____

DETAILED ACTION

Claim Objections

1. Claims 36 and 41 are objected to because of informalities, which can be corrected as follows: With respect to claim 36, the first and third occurrences of "elongated member" should be replaced by --connector--. With respect to claim 41, line 1, "41" should be replaced by --40--. Appropriate correction is required. The claims were examined as if these corrections were made.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 23-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 23, it is not certain whether or not a "connector" is a structural part of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, 20, 21, 23-25, 27, 37, 42, 43, 46, 48, 65, 66, 91-94, 96, 105, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Montague et al.

(5,688,272). With respect to claims 2, 5, 20, 21, 23-25, 27, 37, 42, 43, 46, 48, 65, and 66, Montague discloses, in figures 6 and 7, a connector (204) or transverse connector (of bone or the spine) for an elongated member (R) having a body (30), an opening (32) in the body configured to hold the elongate member, an engager (40) with a surface (47) of the cam system, and an engaging mechanism or a cam system (12) with a portion (40) angulated within the body substantially perpendicular to a longitudinal axis of the body, where removal of the cam system is inhibited by a nut (43) and the engagement portion (12), where a drive tool (e.g., an Allen head wrench—see col. 9, lines 5-10) is used to rotate the cam system (at the engager). With respect to claims 91-94, 96, 105, and 106, Montague et al. disclose, in figure 7, a bone stabilization system (10) and a method of attaching a transverse connector to an elongated member, where the system and method include first and second elongated members (R), first and second fixation elements (200), and a connector (11) of fixed length and having a cam system (12, 40, 43) coupling the connector to the elongated members.

6. Claims 1, 15, 16, 22, 42, 60, 61, 64, 67, 70, 77, 88-90, and 102-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner (5,304,179). Wagner discloses, in the figures, a connector and a method of forming a connector, where the connector and the method include a substantially unbendable body (10) with first and second sections (22) and a fastening system (18) or fastener, first and second openings (24) in the body for receiving elongated members (14), and a cam system (54) in communication with the first opening an configured to extend an engager (16) into the first opening, where the longitudinal axis of the cam system is substantially

perpendicular to the longitudinal axis of the body, where the connector is a transverse connector of a bone or spinal stabilization system, where a threaded connection is not formed between the cam system and the body, and where the method includes inhibiting removal of the cam system from the cam system opening.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4, 27, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. in view of Tornier et al (5,662,651). Montague et al. disclose the invention substantially as claimed, but do not disclose a connector with an opening surface that contacts an elongated member, where the surface is textured. Tornier et al. teach, in figure 1, a connector (3) with a textured surface (3d) for contacting an elongated member. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tornier et al., to texturize the opening

surface of the connector of Montague et al. Such a modification would make for a more secure connection (without rotation of the elongated member) between the connector and elongated member.

9. Claim 95 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. Montague et al disclose the invention substantially as claimed but do not disclose elongated members that have portions, which are unitary, bent, and contoured. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include such elongated members. Such elongated members can be applied in spinal fixation, depending on the degree of curvature in a vertebral column.

Allowable Subject Matter

10. Claims 3, 6-14, 17-19, 45, 47, 49-59, 62, 63, 68, 69, 71-76, 78-87, and 97-101 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 26, 28-36, and 38-41 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses, *inter alia*, a connector with a body, an engager, a cam system, first and second elongated members, and first and second fixation elements, where the engager has a textured

surface for contacting an elongated member; where the engager extends into an opening in the body, when the cam system is rotated; where the connector includes a vibrational, visual, or pin indicator that the cam system is engaged with the body, where the body is bendable, where the cam system is positioned between the opening and the second opening, where the cam system is angulated within the connector greater than 45 degrees relative to a longitudinal axis of the connector and less than perpendicular, where the opening has an open side that allows an elongated member to be top loaded onto the connector, where the fastening system for section of the connector comprises a set screw or a collet and a collar, and where the connector comprises first and second, movable sections and a fastening system when combined with the fixation elements, elongated members, and cam system.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.



Julian W. Woo
Primary Examiner

September 8, 2003